Improving the Security of High-Consequence Microbial Agents and Toxins

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U.S. Biosecurity Drivers

- **U.S. Counterterrorism Bill, November 2000 (S. 3205)**
  - **"Current controls on the transfer and possession of biological pathogens that could be used in biological weapons are inadequate."**
  - **"Standards for the storage, transport, and handling of biological pathogens should be as rigorous as the current standards for the physical protection and security of critical nuclear materials."**
- **U.S. Appropriations Bill, September 2001 (H.R. 2500)**
  - **Required "enhanced standards for physical protection and security of biological pathogens…at research laboratories in the U.S."**
- **U.S. Bioterrorism Preparedness Act of 2001**
  - **S. 1765 now in conference with H.R. 3448**
  - **Enhanced control of biological agents and toxins**
  - **Biosecurity upgrades at USDA**
  - **Biosecurity upgrades at HHS**
- **U.S. has indicated that the Biological Weapons Convention (BWC) could be strengthened by States Parties' adopting and implementing "security standards for pathogenic microorganisms"**

Well Established Biosafety Culture in U.S.

- CDC/NIH manual *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) – 4th edition
  - Gold standard for safely conducting microbiological research
  - Significant reduction in reported biosafety incidents
  - Select Agent List well respected

- Biosafety
  - Objective: *to reduce or eliminate exposure of laboratory workers or other persons and the outside environment to potentially hazardous agents involved in microbiological or biomedical facility research*
  - Strategies: implementing various degrees of laboratory "containment," or safe methods of managing infectious materials in a laboratory setting
  - Elements of safety containment
    - Biosafety levels (BSL 1-4)
    - Laboratory practice and technique
    - Safety equipment (primary barriers)
    - Facility design and construction (secondary barriers)

- WHO *Laboratory Biosafety Manual* – 2nd edition
  - Same elements as BMBL, many derived directly from BMBL

Existing Security Standards are Not Appropriate

- **Standards for Special Nuclear Materials (DOE) are not appropriate for biological research**
  - **Pathogens at laboratory facilities exist in nature and can be obtained from hundreds of laboratories around the world**
  - **Absolute amount of any given organism in an active biomedical research facility cannot be reliably quantified**
  - **Strategically significant quantity of pathogenic material can be obtained from a single cell because it can be easily cultured with commercially available equipment**
  - **Organisms cannot be identified by current standoff technology because they do not emit detectable energy**
- **Standards for generic critical infrastructure (DOJ) would not provide adequate protection**
  - **Focus on external protection – not on insider protection**
- **Appendix F of the BMBL provides inadequate guidance**

Need for Security Standards Tailored to Biomedical Research

- Extensive perimeter and inventory control systems may jeopardize critical research and will not provide adequate protection

- No one U.S. agency can claim a monopoly over biomedical research or thus biosecurity
  - Nature of the business demands that various agencies, as well as many universities and private companies, collaborate and communicate with each other as well as transport organisms from one to another

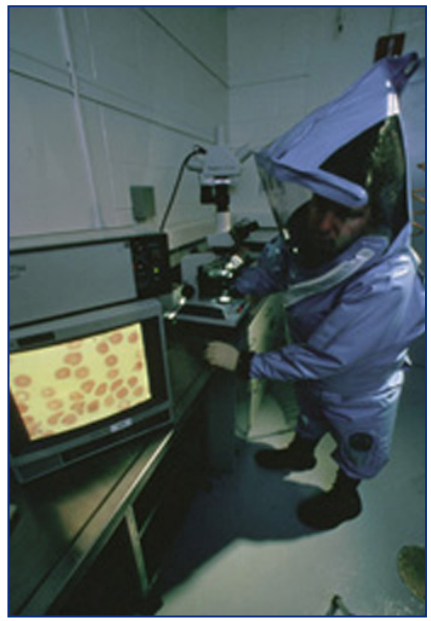
- Biological Laboratory and Transportation Security (BLTS) standards would
  - Address the unique targets, threats, and risks associated with biomedical research
  - Recognize the legitimate variation in operating procedures of sites that work with high-consequence microbial agents and toxins
  - Allocate security resources wisely
  - Apply to entire U.S. biomedical research community

Defining Biosecurity

- **Objective:** ***to protect against the theft or diversion of high-consequence pathogens and toxins, which could be used by someone with malicious intent for bioterrorism or biological weapons proliferation***

- **Strategies**
  - **Identify targets for protection, assess general threats and local vulnerabilities**
  - **Integrate security technologies, procedures, and protocols to protect high-consequence pathogens**

- **Elements**
  - **Facility security, personnel reliability, pathogen accountability, transportation security, information security, scientific program oversight**

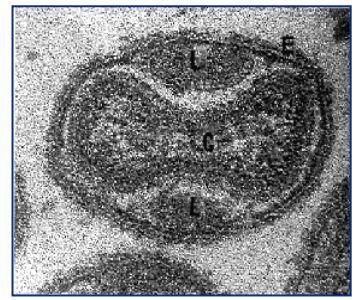


What would BLTS Standards Include?

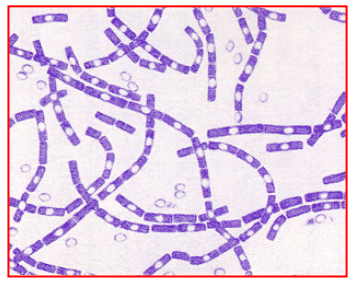
- **Target identification methodology**
  - **What is a high-consequence pathogen/toxin (HCP) and critical HCP information?**
- **Scientific program oversight requirements**
  - **What types of research should be reported, and what federal agency should have oversight responsibility?**
- **Threat assessment methodology**
  - **Who would try to steal or divert a HCP?**
- **Risk assessment methodology**
  - **What vulnerabilities exist at a specific facility or system?**
- **Security system design methodology**
  - **What technologies, policies, and procedures will reduce risk to an acceptable level?**

Target Identification

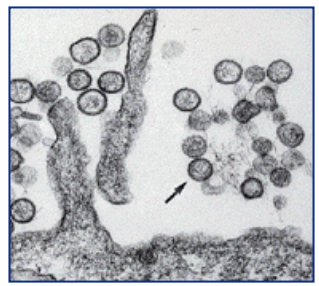
- **What are High-Consequence Pathogens and Toxins (HCPs)?**
  - **Existing lists are not appropriate**
    - **Biosafety Levels not based on security**
    - **Select Agent List (1997) excludes plant, animal, and some zoonotic pathogens**
    - **Restricted Animal Diseases List includes many non-HCPs**
  - **Need for an algorithm or a list that can be dynamic over time**
  - **S.1765 requires the creation of a list of biological agents and toxins with the potential to pose a severe threat to public health and safety**
- **How to define HCP information that should be protected?**
  - **Formulas for weaponizing pathogens or for creating new, lethal organisms**



Variola major



Bacillus anthracis



Sin Nombre Virus (causal agent for HPS)

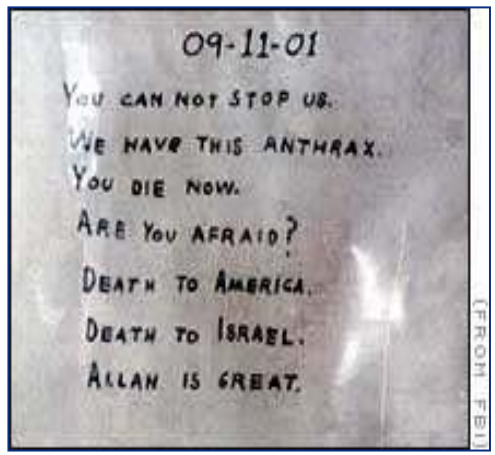
Scientific Program Training and Oversight

- **Reporting system for locations that store, use, and/or transport high-consequence pathogens and toxins (HCPs)**
  - **Organisms**
    - **Not a rigorous inventory but a mass accountability system**
    - **Could include sequencing of genomes of certain strains**
  - **Individuals**
    - **Who has access to HCPs and what background screening have they been subject to?**
  - **Research**
    - **Is there certain biodefense work that is a higher security risk?**
    - **Should there be oversight/coordination to ensure that this work does not jeopardize international commitments?**
- **Those facilities that store, use, and/or transport HCPs would be required to meet certain biosecurity objectives**

Threat Assessment

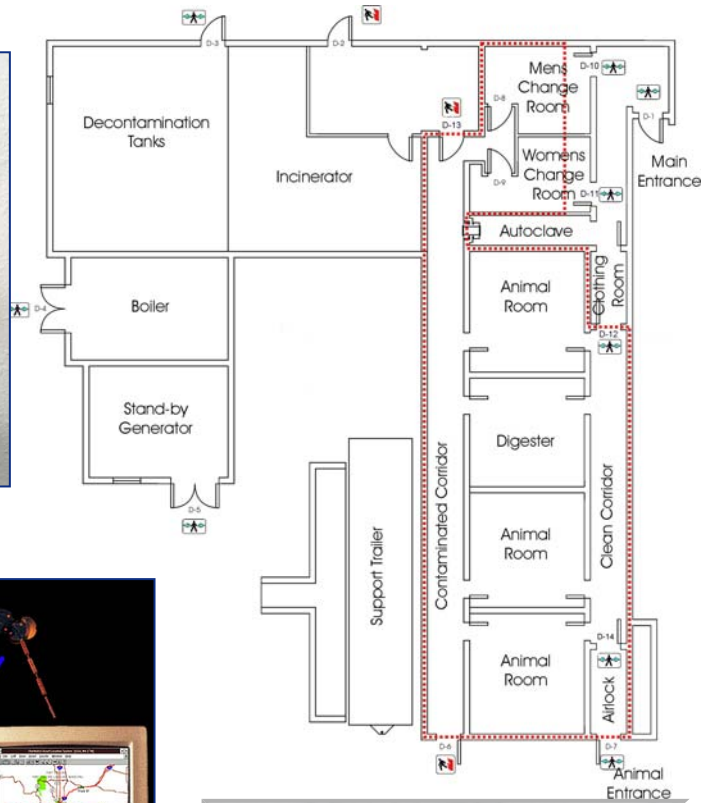
- **Threat assessment should drive security system design**
  - **A management tool: higher the threat, more substantial security should be to provide protection**
  - **Should be reviewed regularly with appropriate law enforcement agencies**

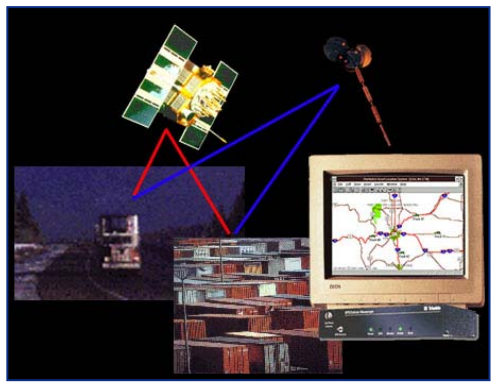
- **Against what should high-containment biomedical research facilities and HCPs be protected?**
  - **Insiders**
  - **Animal rights groups**
  - **Anti-GMO groups**
  - **Terrorist commandoes**



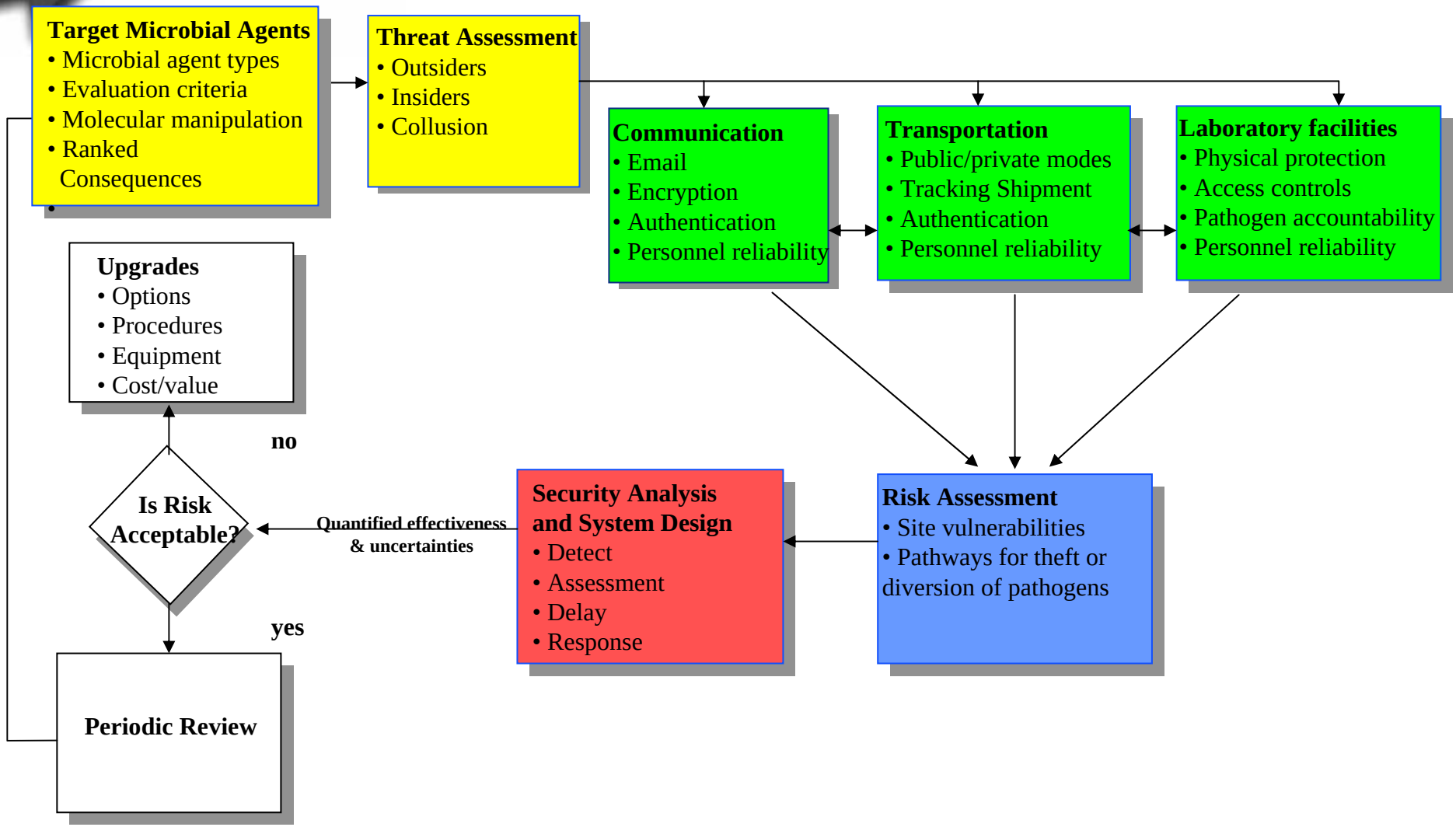
Risk Assessment and Security System Design

- **Facilities**
  - Access control systems
  - Intrusion detection systems
  - Pathogen chain of custody
  - Personnel reliability
  - Response forces
- **Transportation**
  - Tamper-indication packaging
  - Real-time tracking
  - Personnel reliability
- **Information**
  - Classification guidelines
  - Firewalls
  - Encryption, authentication
  - Personnel reliability





Framework for BLTS of High-Consequence Microbial Agents and Toxins



A BLTS Methodology?

- **Graded approach**
  - High-consequence assets receive highest protection
  - Integrated system: technologies, systems, procedures, people
- **To protect against the insider threat**
  - Scientific program oversight
  - Personnel reliability program
  - Controlled access to high-containment areas
  - Chain-of-custody procedures and material transfer agreements for high-consequence pathogens in transit
- **To protect against the outsider threat**
  - Detection of access through likely avenues of approach into high-consequence areas
  - Assessment of alarms
  - Response force capability

Potential Benefits to the U.S.

- **Development and implementation of national BLTS standards**
  - **Improved security of HCPs at facilities and in transit in the U.S. and wherever else the standards are implemented**
- **National reporting and registration system for facilities that store, use, and/or transport high-consequence pathogens**
  - **Knowledge of where HCPs are and who is working with them**
  - **Knowledge of location and individuals working on biodefense or other vulnerable projects**
- **Support the U.S. position that security standards would combat the proliferation of biological weapons and strengthen the BWC**